

REMARKS

Reconsideration and withdrawal of the restriction requirement is respectfully requested in view of the remarks presented herewith.

The Office Action has required restriction from among the following Groups:

- I. Claims 2-7, 24, and 27 in total, and claims 1, 23, and 26 in part, drawn to the GCR1 (Fragilis) polypeptide, classified in class 530, subclass 350.
- II. Claims 11-13, 18, and 21 in total, and claims 8-10, 17, and 20 in part, drawn to the GCR1 (Fragilis) nucleic acid, classified in class 536, subclass 23.5.
- III. Claims 35 in part, and 36, drawn to antibodies specific for GCR1 (Fragilis) polypeptide, classified in class 530, subclass 387.1.
- IV. Claims 29-34, 37, and 41-43, each in part, drawn to methods of identifying pluripotent cells comprising detecting presence of a GCR1 (Fragilis) polypeptide, classified in class 435, subclass 7.21.
- V. Claims 46-49 and 51-53, each in part, drawn to transgenic non-human animals comprising GCR1 (Fragilis) nucleic acid classified in class 800, subclass 8.
- VI. Claim 50 in part, drawn to a method of identifying a compound which is capable of interacting specifically with a GCR1 (Fragilis) protein comprising use of a transgenic non-human animal comprising GCR1 (Fragilis) nucleic acid, classified in class 800, subclass 3.
- VII. Claim 54 in part, drawn to a nucleic acid construct for functionally disrupting a GCR1 (Fragilis) gene in a host cell, classified in class 536, subclass 24.5.
- VIII. Claims 38 and 39, drawn to a pluripotent cell identified by detecting presence of a GCR 1 (Fragilis) polypeptide, classified in class 435, subclass 325.
- IX. Claims 25 and 28 in total, and claims 1, 23, and 26 in part, drawn to the GCR (Stella) polypeptide, classified in class 530, subclass 350.
- X. Claims 14-16, 19, and 22 in total, and claims 8-10, 17, and 20 in part, drawn to the GCR2 (Stella) nucleic acid, classified in class 536, subclass 23.5.
- XI. Claim 35 in part, drawn to antibodies specific for GCR2 (Stella) polypeptide, classified in class 530, subclass 387.1

- XII. Claims 29-34, 37, and 41-43, each in part, drawn to methods of identifying pluripotent cells comprising detecting presence of a GCR2 (Stella) polypeptide, classified in class 435, subclass 7.21.
- XIII. Claims 46-49 and 51-53, each in part, drawn to transgenic non-human animals comprising GCR2 (Stella) nucleic acid, classified in class 800, subclass 8.
- XIV. Claim 50 in part, drawn to a method of identifying a compound which is capable of interacting specifically with a GCR2 (Stella) protein comprising use of a transgenic non-human animal comprising GCR2 (Stella) nucleic acid, classified in class 800, subclass 3.
- XV. Claim 54 in part, drawn to a nucleic acid construct for functionally disrupting a GCR2 (Stella) gene in a host cell, classified in class 536, subclass 24.5.
- XVI. Claims 40, 44, and 45, drawn to a method of isolating a gene specifically expressed in a pluripotent cell, classified in class 435, subclass 91.1.

Applicants hereby elect Group I, with traverse, for prosecution on the merits.

The Office Action states that Groups I-VII are unrelated to groups IX-XV because Groups are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different groups each recite or utilize distinct polypeptides, designated GCR1 (Fragilis) or GCR2 (Stella), respectively. The Office Action alleges that these two polypeptides are not disclosed as being related to one another structurally or functionally, their only relationship being that they are expressed in the same cell. The Office Action thus finds that these polypeptides (Groups I and IX), their respective encoding nucleic acids (Groups II and X), antibodies (Groups III and XI), transgenic animals (Groups V and XIII), constructs (Groups VII and XI), and all claimed methods of using (Groups IV, VI, and XII, XIV) are allegedly patentably distinct.

The Office Action further states that Groups I-XV and XVI are allegedly unrelated as Group XVI is a method of gene discovery that does not rely upon, utilize, or recite any of the products or methods of groups I-XV.

In addition, it is alleged that Groups I, II, III, V, VII, and VIII are independent and distinct, each from each other, because they are products that possess characteristic differences in

structure and function and each has an independent utility that is distinct for each group which cannot be exchanged.

The polypeptides of Group IX, the nucleic acids of Group X, and the antibodies of Group XI, the transgenic animal of Group XII, the nucleic acid construct of Group XV, and the pluripotent cell of Group VIII are also alleged to be independent and distinct, each from each other for reasons that are analogous and parallel to those set forth above for Groups I, II, III, V, VII, and VIII.

Groups I-III, VIII and IV are allegedly related as product and process of use and are allegedly distinct because each of the products of Groups I-III and VIII could be used in processes other than the cell identification process of Group IV, and conversely, pluripotent cells can be identified by means that do not utilize the products of Groups I-III or VIII or the method of Group IV.

Similarly, the Office Action alleges that Groups IX-XI, VIII and XII are related as product and process of use and are allegedly distinct because each of the products of Groups IX-XI and VIII could be used in processes other than the cell identification process of Group XII, and conversely, pluripotent cells can be identified by means that do not utilize the products of Groups IX-XI or VIII or the method of Group XII.

Groups V and VI are also allegedly related as product and process of use and are allegedly distinct because the group of Group V, a non-human transgenic animal comprising GCR1 (Fragilis) nucleic acid can be used in processes other than the compound identification process of Group VI and conversely, a compound that specifically interacts with GCR1 (Fragilis) could be identified without the use of a transgenic animal.

Groups XIII and XIV are allegedly related as product and process of use and are allegedly distinct because the group of Group XIII, a non-human transgenic animal comprising GCR2 (Stella) nucleic acid can be used in processes other than the compound identification process of Group XIV, and conversely, a compound that specifically interacts with GCR2 (Stella) could be identified without the use of a transgenic animal.

The Office Action states that Groups IV and VI are allegedly unrelated as the claims of Groups IV and VI are not usable together, they use different products and have different functions.

Groups XII and XIV are allegedly unrelated for reasons that are analogous and parallel to those set forth in the Office Action for Groups IV and VI.

Groups I-III, VII, VIII are allegedly unrelated to Group VI because none of the products of Groups I-III, VII, VIII are required or utilized in the method of Group VI.

Groups IX-XI, XV, VIII are allegedly unrelated to Group XIV because none of the products of Groups IX-XI, XV, VIII are required or utilized in the method of Group XIV.

Groups V, VII are allegedly unrelated to Group IV because none of the products of Groups V, VII are required or utilized in the method of Group IV.

Groups XIII, XV are allegedly unrelated to Group XI because none of the products of Groups XIII, XV are required or utilized in the method of Group XI.

The MPEP lists two criteria for restriction to be proper. First, the invention must be independent or distinct. MPEP §803. Second, searching the additional invention(s) must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden...even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action alleges that “because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, , and the search required for any of Group I-XVI is not required for any other of Group I-XVI, restriction for examination purposes is indicated as proper. However, a number of the groups have been classified under common search classes, which contradicts the above statement. Therefore, it is respectfully submitted that at least a subset of the groups that are commonly classified should be subject to rejoinder.

For example, Groups I and IX have been classified in class 530, subclass 350; Groups II and X have been classified in class 536, subclass 387.1; Groups III and XI have been classified in class 530, subclass 387.1; Groups IV and XII have been classified in class 435, subclass 7.21; Groups V and XIII have been classified in class 800, subclass 8; Groups VI and XIV have been classified in class 800, subclass 3; and Groups VII and XV have been classified in class 536, subclass 24.5. The fact that these selected Groups fall under the same search classification indicates that it would not be an undue burden on the Examiner to search and examine the subject matter of the present invention, contrary to the assertions made in the Office Action.

Furthermore, any burden placed on the Examiner by the search and examination of more than a single group would be far less than the prejudice and burden placed on the Applicant should restriction be maintained such that the Applicant must file and prosecute over 15 separate applications in order to protect their invention.

The claims as originally filed represent a web of knowledge and continuity of effort that merits examination as a single invention. Additionally, a search of the commonly classified Groups is necessarily believed to be coextensive, as searches of the subject matter of these Groups would consequently and inextricably encompass a search of the claims included in each Group that encompasses a common classification.

Accordingly, as Applicants have elected the claims of Group I, with traverse, Applicants request that Group I be at least rejoined with those Groups similarly classified, such that the claims of Groups I and IX are searched and examined together.

In view of the remarks herein, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met. Indeed, the search and examination of each commonly classified Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

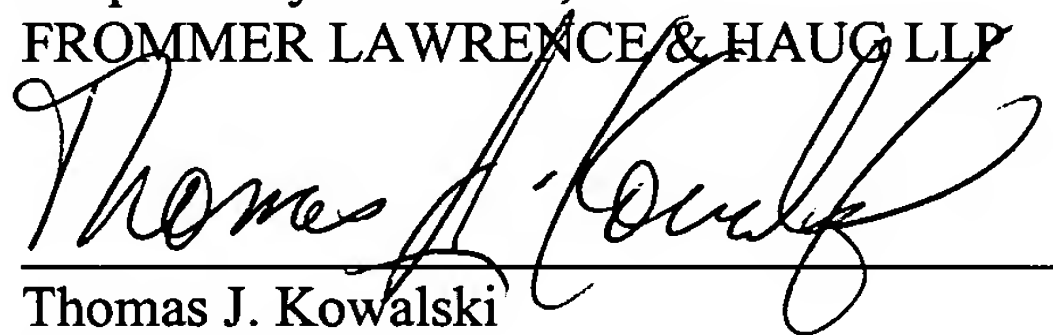
In view of the foregoing, Applicants respectfully request reconsideration and withdrawal, or at least modification, of the restriction requirement, such that, at the least, the claims of Group IX are searched and examined with the claims of Group I.

CONCLUSION

Reconsideration and withdrawal, or modification of the restriction requirement, and a prompt and favorable examination on the merits, is respectfully requested.

Respectfully submitted,
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